EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2013
EMA/310484/2013

Resources for issuing treatment recommendation during shortages of medicinal products

1. Introduction

This document aims to summarise the information sources that can be used for the preparation of clinical recommendations during a shortage of a medicinal product, such us:

Use of the affected medicinal product with amended dosing, use of different formulations, strengths, and/or administration routes, management of different safety or efficacy profile of amended dosing, potential for medication errors, particularities of administration, gender- or age- related differences in the clinical profiles, specific risk minimisation activities, off label use, identification of an alternative medicinal product that could temporarily replace the affected one, local versus EU recommendations, the need for short or long term measures, etc.

2. Information sources

2.1. Specific shortage-related sources

- GMP inspection report identifying or investigating a shortage
- Outcome of an GMP inspection and regulatory assessment
- Quality defect reports and assessment
- Manufacturing problem report and assessment

2.2. Original MAA and post-authorisation procedures

Quality documents

- Physicochemical properties of Active Substance e.g. solubility, stability etc - (3.2.S.1.3)
- Possibility to prepare magistral / extemporaneous formulation - (literature, 3.2.P.2.2.1)
- Manufacturing supply chain as described in Part 1A of the dossier

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

(Non)clinical documents

- CSR of dose finding studies
- CSR of drug-drug interaction studies
- CSR of population studies
- CSR pharmacokinetic trials
- CSR of pivotal studies (comparator studies)
- CSR of studies included in the paediatric investigation plan (PIP)
- Risk management plan (RMP)
- Periodic Safety Update Reports (PSURs)
- PhV inspection reports
- Outcome of the PhV inspection and the regulatory risk assessment
- Nonclinical data

2.3. The MAH of the product under shortage

- Availability of other strengths or pharmaceutical forms of the same product
- The MAH's risk assessment of the clinical use of the medicinal product with a defect/GMP noncompliance
- Information on the status of the remaining stock of the affected medicinal products
- Distribution plans of the remaining product in the EU and world wide
- Regular updates on the stock situation of the affected medicinal product (per country)
- Reports on the progress of the corrective actions taken to revert the shortage cause
- Information on the estimated timing of the return to normal production levels
- The MAH's risk assessment of switching patients to other alternatives
- Relevant clinical information:
    - experience from previous drug shortage(s)
    - contingency plan on how to deal with a shortage
    - experience with amended dosing, e.g. lower dose
    - experience with other medicinal product within the same indication
    - unpublished clinical data,
    - on-going investigations and clinical trials
- Relevant nonclinical information

2.4. The MAH of the alternative product

- Any clinical comparative data between the alternative and the shortage product (on-going investigations, unpublished studies, etc.)
- Information on the status of the current and future stock situation, nationally and within the EU, of the alternative medicinal product, inclusive of generics
- The prognosis to cope with possibly increased demand

2.5. External experts and other sources of information

- Individual clinical specialists and experts in the given therapeutic area
- Physicians' organisations
- Patient groups
- Information on market share
- National databases on drug utilisation